Opportunity Title: FDA Postgraduate Research Opportunity in Engineered Therapeutic Proteins
Opportunity Reference Code: FDA-CBER-2020-0028

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-CBER-2020-0028

How to Apply A complete application consists of:

- An application
- Transcripts – Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- One educational or professional recommendation

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CBER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 9/10/2020 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

A research opportunity is currently available with the Office of Tissues and Advanced Therapies (OTAT), at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project is broadly related to the immunogenicity of therapeutic proteins. Proteins are increasingly used in therapy but they often elicit an undesirable immune response that reduces their efficacy and can compromise the safety of the patient. This laboratory uses in silico, in vitro and ex vivo tools and approaches to understand why the same drug elicits immune responses in patients and not in others. The selected participant will be involved with a multi-disciplinary group of scientists to develop, refine and validate these tools.

Through this project, the participant will have the opportunity to learn new skills and technologies in the laboratory, participate in seminars and apply these skills to scientific issues with direct applications in the clinic and during drug development. During the project, the participant will be actively encouraged to present the research at internal and external meetings and publish the findings in peer-reviewed journals. The training will be useful for individuals with an undergraduate degree seeking to apply to graduate or medical school or seeking careers in academia or industry.

References:

1. H.A.D. Lagassé, H. Hengel, H., B. Golding, & Z.E. Sauna. Fc-Fusion drugs have Fc?R/C1q binding and signaling properties that may affect their immunogenicity. AAPS J. 21: 62, 2019
2. V.L. Simhadri, J. McGill, S. McMahon, J. Wang, H. Jian & Z.E. Sauna. Prevalence of Pre-existing Antibodies to CRISPR-associated Nuclease Cas9 in the US Population. Mol Ther Methods Clin Dev. 10: 105-112, 2018
3. Z.E. Sauna, D. Lagassé, J. Pedras-Vasconcelos, B. Golding & A.S. Rosenberg. Evaluating and mitigating the immunogenicity of therapeutic proteins. Trends Biotechnol 36: 1068-1084, 2018
4. D. Levin, H.A.D Lagassé, E. Burch, S. Strome, S. Tan, H. Jiang, Z. E. Sauna & B. Golding. Modulating immunogenicity of factor IX by fusion to an immunoglobulin Fc domain: a study using a hemophilia B mouse model. J. Thromb. Haemost. 15: 721-734, 2017
5. K. Lamberth, S. Louise Reedtz-Runge, J. Simon, K. Klementyeva, G.S. Pandey, S.B. Padkjær,

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V. Pascal, I.R. León, C.N. Gudme, S. Buus & Z.E. Sauna. Post-hoc assessment of the immunogenicity of bioengineered Factor VIIa demonstrates utility of preclinical tools. Sci. Transl. Med. 9: eaag1286, 2017

6. G.S. Pandey, C. Yanover, L.M. Miller-Jenkins, S. Garfield, S.A. Cole, J.E. Curran, E.K. Moses, N. Rydz,V. Simhadri, C. Kimchi-Sarfaty, D. Lillicrap, K. Viel, T. Przytycka, G.F. Pierce, T.E. Howard & Z.E. Sauna. Synthesis of FVIII in Hemophilia-A patients with the intron-22-inversion may modulate immunogenicity. Nature Med. 19: 1318-1324, 2013
7. C. Yanover, N. Jain, G. Pierce, T.E. Howard & Z.E. Sauna. Pharmacogenetics and the immunogenicity of protein therapeutics Nature Biotechnol. 29, 870-873, 2011

Anticipated Appointment Start Date: July 1, 2020

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The initial appointment is for one year, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications

The qualified candidate should have received a bachelor's degree in one of the relevant fields, or be currently pursuing the degree and will reach completion by the appointment start date. Degree must have been received within five years of the appointment start date.

Basic skills in molecular biology, cell culture, assays, etc. are desired.

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Bachelor's Degree received within the last 60 months or anticipated to be received by 7/1/2020 11:59:00 PM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (2 👁)
  - **Life Health and Medical Sciences** (8 👁)